IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR JUDGMENT ON PARTIAL FINDINGS REGARDING PROXIMATE CAUSATION

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INTRODUCTION

In order to withstand judgment on partial findings under Rule 52(c), Plaintiffs were required to produce evidence establishing that Defendants' alleged wrongdoing is a direct cause of the alleged public nuisance—which, according to Plaintiffs, consists of a present-day opioid abuse problem in Cabell/Huntington.[1] The undisputed record evidence shows that is not the case.

Plaintiffs allege that Defendants shipped too many prescription opioid pills into Cabell/Huntington. But the record is clear that Defendants did not cause the increase in the volume of orders placed by Defendants' pharmacy customers. Instead, the undisputed evidence is that the increase in the amount of opioid medicines ordered by Defendants' customers and shipped by Defendants was overwhelmingly due to an increase in good-faith prescribing by doctors, triggered by a change in the standard of care for the treatment of pain. The record is clear that Defendants (1) played no role in that change to the standard of care and (2) have neither the duty nor the ability to second-guess the prescribing decisions of doctors. Accordingly, Defendants were not a proximate cause of increased prescription opioid availability in Cabell/Huntington.

Plaintiffs also allege that Defendants failed to maintain effective controls against diversion—*i.e.*, the transfer of controlled substances to illicit channels. The evidence shows that there are two principal forms of diversion at issue in this case. *First*, diversion can occur ***after*** opioid medicines are delivered by Defendants to their DEA-registered pharmacy customers and dispensed by those pharmacies to patients—such as when a patient sells or gives away unused pills to family or friends. The record is clear that this was the principal form of opioid diversion in

[1] Plaintiffs have waived any claim for past damages, and therefore cannot recover absent proof that Defendants are a cause of an ongoing, present-day opioid abuse problem in Cabell/Huntington. *See* Mem. of Law in Support of Defs.' Mot. for Judgment on Partial Findings Regarding Abatement ("Abatement Mot.") at Part I.A.

Cabell/Huntington, and that it indisputably was not caused by Defendants. Moreover, where such diversion is concerned, the intervening (criminal) acts of doctors, pharmacists, illegal drug diverters, and illegal drug users render Defendants' connection to any resulting harm too remote and attenuated as a matter of law.

Second, diversion can occur at the pharmacy level—for example, if a pharmacist dispenses prescription opioid medicines to a patient in the absence of a bona fide prescription and in violation of the pharmacist's legal duties. But Plaintiffs presented no evidence that any Defendant ever shipped prescription opioids to a pharmacy in Cabell/Huntington that the Defendant knew or should have known was engaged in diversion. Indeed, Plaintiffs did not present any evidence that any of Defendants' pharmacy customers in Cabell/Huntington were in fact engaged in diversion. And, finally, Plaintiffs could not establish that Defendants proximately caused any harm flowing from any illegal acts of pharmacists and others that occur ***after*** Defendants cease having any control over the medicines they deliver. Accordingly, Plaintiffs have failed to prove that Defendants' alleged wrongdoing was the proximate cause of any pharmacy-level diversion in Cabell/Huntington.

Even further afield are Plaintiffs' allegations relating to the abuse of illicit, non-prescription opioids by Cabell/Huntington residents. The record is clear that Cabell/Huntington does not have a current, widespread prescription opioid abuse problem. Rather, since no later than 2013, Cabell/Huntington's opioid problem overwhelmingly consists of abuse of ***illegal*** opioids such as heroin and illicit fentanyl.

Defendants do not distribute these illegal narcotics—drug traffickers and drug dealers do. The record thus makes clear that the immediate causes of any harms flowing from this illicit drug use are (i) the traffickers and dealers who deliver those illegal drugs to Cabell/Huntington residents

and (ii) the individuals who illegally ingest those illicit narcotics—not Defendants. At a minimum, any causal chain purporting to connect Defendants' shipments of FDA-approved medicines to DEA-registered pharmacies with the later abuse of illegal, non-prescription opioids by Cabell/Huntington residents is too remote and attenuated as a matter of law. Accordingly, Plaintiffs—who did not even seriously attempt to identify any wrongdoing by Defendants after 2013—have failed to establish that Defendants are a proximate cause of any present-day, illegal opioid abuse problem in Cabell/Huntington.

FACTUAL BACKGROUND

Defendants play an important role in the healthcare supply chain, including by ensuring that patients can access needed medicines on a timely basis.[2] But their role with respect to controlled substances is narrow. Defendants buy prescription opioids from DEA-registered and State-licensed manufacturers and sell them to DEA-registered and State-licensed pharmacies. They do not prescribe opioids to patients (that is the job of a licensed medical professional), dispense opioids to patients (that is the job of a licensed pharmacist), or interact with doctors or patients regarding their decisions about which medications to prescribe or use.[3]

[2] *See, e.g.*, 5/17 Tr. at 33:11–34:15 (ABDC's Vice President of Diversion Control and Security, David May, describing the concept of "just in time delivery," whereby wholesale distributors provide daily ordering services to licensed dispensers); 6/9 Tr. at 87:12–19 (Mr. Rannazzisi agreeing that "it's vital that an adequate and uninterrupted supply of pharmaceutical controlled substances be available for effective patient care"), 155:8–19 (Mr. Rannazzisi agreeing that "distributors play an important role in insuring an adequate and uninterrupted supply of prescription opioids" and that "if a patient doesn't get the medication they need, there's a breakdown in the system").

[3] *See, e.g.*, 5/4 Tr. at 90:19–21 (Dr. Corey Waller testifying that distributors do not interact directly with patients); 5/25 Tr. (Oriente) at 30:13–22 ("Q. When it comes to talking with prescribers, talking with doctors about the medicines they're prescribing, and which ones they should be prescribing, is that something McKesson does? A. No, we do not. Q. Does McKesson interact directly with patients in terms of talking with them about what medicines they should use? A. No, McKesson does not."); 5/13 Tr. (Zimmerman) at 155:12-20 ("Q…. Does AmerisourceBergen ever

Beginning in the 1990s, there was a movement in the medical community to address the widespread undertreatment of pain.[4] Pain advocacy groups encouraged doctors to treat pain as the "fifth vital sign," *see* Trial Ex. MC-WV-02079 (Compton 2019) at 6, and a number of healthcare organizations and state medical boards—including the West Virginia Board of Medicine—promulgated treatment guidelines that approved and encouraged the use of prescription opioids to treat both acute and chronic pain.[5] As a result, doctors across the country and in Cabell/Huntington began to prescribe opioids in greater volumes and for a broader range of conditions than ever before, including for the long-term treatment of chronic pain.[6]

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interact with the patient? A. No. Q. Is AmerisourceBergen ever consulted by a doctor when that doctor is making prescribing decisions? A. No. Q. Does AmerisourceBergen make medical decisions? A. No.").

[4] *See* Trial Ex. MC-WV-02079 (Compton 2019) at 5–6; *see also* Trial Ex. MC-WV-02111 (Responsible Opioid Prescribing) at 111 (2007 book by Dr. Scott Fishman—which was distributed to every licensed prescriber in West Virginia—stating that "[t]here is no debate among public health experts about the undertreatment of pain, which has been recognized as a public health crisis for decades").

[5] *See, e.g.*, Trial Ex. MC-WV-01219 (1997 Position Statement by the West Virginia Board of Medicine) at 1 (stating that "opioids are appropriate treatment for chronic non-malignant pain in selected patients"); Trial Ex. MC-WV-01218 (2005 West Virginia Board of Medicine Guidelines) at 1–2 (stating that "controlled substances including opioid analgesics may be essential in the treatment of acute pain … and chronic pain, whether due to cancer or non-cancer origins"); Trial Ex. DEF-WV-01935 (2013 West Virginia Board of Medicine Guidelines) at 3 (stating that "opioid analgesics are useful and can be essential in the treatment of acute pain … as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes").

[6] *See* Trial Ex. MC-WV-02079 (Compton 2019) at 5–6; *see also* Trial Ex. P-44223 (2018 Opioid Response Plan for the State of West Virginia) at 9 ("A critical factor in fueling the national opioid epidemic is the rapid rise in opioid prescriptions for pain. From 1999 to 2012, opioid prescribing increased fourfold … West Virginia has experienced some of the highest rates of opioid prescribing in the nation."); 5/21 Tr. at 27:10–16 (Dr. Joseph Werthammer agreeing that "during that period where pain was considered the fifth vital sign, … opioids [were] prescribed more liberally").

Dr. Rahul Gupta, the former West Virginia Commissioner of Public Health, described a "culture" of overprescribing and "attempting to reduce pain … to zero for every American [and] every West Virginian" that was "not easy to change." 5/6 Tr. at 89:8–17, 90:20–24, 136:5–10. Even though doctors in retrospect may have been overprescribing, the evidence shows that the overwhelming majority were doing so based on their good-faith professional judgment that opioid treatment was medically appropriate. For instance:

- Dr. Gupta testified that "there were more good doctors than bad doctors [in West Virginia]," and that "[t]heir intent was to help their patient because that was the culture. That was the education. That was the influence. That was their understanding." 5/6 Tr. at 93:20–94:10.

- Dr. Corey Waller agreed, testifying that doctors who were prescribing opioids for chronic non-cancer pain in the mid-2000s "were acting in good faith[.]" 5/4 Tr. at 104:15–20.

- Dr. Katherine Keyes admitted that "the overwhelming majority of doctors prescribe opioids to their patients in good faith." 6/14 Tr. at 71:3–7, 76:8–15.

- DEA has stated that "nearly every prescription issued by a physician in the United States is for a legitimate medical purpose." *See* Trial Ex. DEF-WV-03076 (Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52721) at 7. Plaintiffs' expert James Rafalski agreed with that assessment, 5/26 Tr. at 120:21–121:9, and Joe Rannazzisi—the former Head of DEA's Office of Diversion Control—testified that he told Congress that "99 percent of the doctors are ***perfect***."[7] 6/9 Tr. at 102:4–10; *see also id.* at 102:17–21 (Mr. Rannazzisi agreeing that he "repeatedly" told Congress "that the overwhelming majority of prescribing in America is conducted responsibly").

During this period of increased good-faith prescribing, the aggregate volume of Defendants' opioid distribution increased in Cabell/Huntington and across the country. But as Plaintiffs' own fact and expert witnesses have explained, that increased distribution is simply a reflection of increased prescribing—there is ***"no other way"*** for distribution to increase than for

[7] All emphasis added unless noted.

doctors to prescribe more opioids. 5/26 Tr. (Rafalski) at 242:6–20.[8] Plaintiffs' witnesses have agreed that Defendants have no ability (let alone responsibility) to second-guess the good-faith medical judgments made by doctors. *See, e.g.*, 5/26 Tr. (Rafalski) at 117:8–12 ("Q. The DEA does not expect distributors to second-guess the legitimate medical judgments of prescribers. True? A. Well, I would agree with that, Your Honor….").[9] Plaintiffs have presented ***no evidence*** of any prescription opioid pills shipped by Defendants other than in response to a prescription written by a licensed prescriber.[10] And the DEA never advised Defendants that their distribution volume was too high. *See* 6/9 Tr. (Rannazzisi) at 92:18–21 ("Q. When you were at DEA, did you ever issue guidance to distributors, the healthcare community, doctors that these levels were too high? A. No, I did not.").

To be sure, there is some evidence of prescription opioid misuse and diversion during the period of increased doctor prescribing. *See, e.g.*, 5/27 Tr. at 85:14–15 (Cabell County Sheriff Charles Zerkle testifying that "pills were very prominent in '07 to '10"). But there is no evidence tying any of that misuse or diversion to ***Defendants'*** conduct in shipping prescription opioid

[8] *See also* 5/11 Tr. at 134:24–135:3 (Dr. McCann testifying that prescribing and distribution volumes are "two sides of the same coin"); 6/9 Tr. at 190:8–13 (Mr. Rannazzisi testifying that the opioid crisis "started with prescriptions"); 5/15 Tr. at 206:17–25 (Dr. Keller testifying that, because ARCOS data "shows shipments by distributors to pharmacies" it is a "reflection of the prescribing because orders ultimately fill prescriptions that are written.").

[9] *See also* 5/26 Tr. (Rafalski) at 149:3–13 (Mr. Rafalski agreeing that distributors "don't have access to individual patient prescriptions or individual patient data" and "don't have the information to evaluate the medical need of an individual patient"); 6/9 Tr. (Rannazzisi) at 98:16–19 ("Q. And a distributor cannot make the determination if a controlled substance is medically necessary for a particular patient; correct? A. Yes. And we've never asked a distributor to do that."); 5/4 Tr. at 88:1–21, 90:19–21 (Dr. Waller testifying that wholesale distributors do not make prescribing decisions and do not interact directly with patients).

[10] *See, e.g.*, 5/26 Tr. at 131:6–10 (Mr. Rafalski testifying that he is not aware of any pills shipped by Defendants "other than in response to a licensed prescriber writing a prescription").

medicines to DEA-registered and State-licensed pharmacies in response to prescriptions written by doctors. As Plaintiffs' witnesses have admitted, the prescription opioids that Defendants shipped could not lawfully leave a pharmacy shelf without independent medical judgments by doctors (to prescribe) and pharmacists (to dispense).[11]

Moreover, Plaintiffs' witnesses have conceded that there is no evidence of (1) diversion while prescription opioids were within Defendants' possession or control[12] or (2) diversion at the pharmacy level (*i.e.*, by Defendants' pharmacy customers) in Cabell/Huntington.[13] Instead, the overwhelming evidence is that diversion occurred ***after*** prescription opioids were dispensed to patients, including through the sharing or selling of unused pills among friends and family members.[14] Plaintiffs' putative diversion expert, James Rafalski, conceded that Defendants have

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[11] *See, e.g.*, 5/6 Tr. at 47:5–9, 17–21 (Dr. Gupta testifying that "an opioid pill cannot leave a pharmacy lawfully unless a prescriber decides to write a prescription and the pharmacist decides to dispense it" and that "the total volume of prescriptions … would reflect the total volume of pills that could leave the pharmacy"); 6/11 Tr. at 94:21–95:2 (Dr. Mohr admitting that "a medication that a distributor ships to a pharmacy is simply going to stay on that shelf until a patient comes in with a valid prescription written by a medical professional and requests that to be filled"); 6/14 Tr. (Keyes) at 83:3–8 ("Q. You're aware, I take it, that no matter how many opioids a distributor ships to a given pharmacy, if there's not a prescription from a doctor, those opioids stay on the pharmacy shelf and never reach the community, correct? A. My understanding generally is that that's how it's supposed to work.").

[12] 5/26 Tr. (Rafalski) at 194:17–23 ("Q. That's a form of diversion that can occur from distributors; correct? Robbery, theft? A. Yes. Q. Are you aware of any of that that's impacted Huntington/Cabell relating to any of the distributors here? A. I'm not aware of any robberies or thefts from registrants in Cabell or Huntington, sir.").

[13] *See* 5/26 Tr. at 135:9–13 (Mr. Rafalski, testifying that he is "not offering any opinions about whether diversion occurred at a pharmacy level").

[14] *See, e.g.*, 5/4 Tr. at 174:23–175:5 (Dr. Waller describing how diversion of unused opioid pills occurs between friends and family members); 5/6 Tr. at 91:14–25 (Dr. Gupta describing how the oversupply of prescription opioids caused by doctor overprescribing went unused and ended up being diverted from patients' medicine cabinets); 5/26 Tr. at 199:11–18 (Mr. Rafalski taking no issue with statistics showing that "more than three out of four people who misuse prescription painkillers use drugs prescribed to someone else"); 6/9 Tr. at 141:3–10 (Mr. Rannazzisi confirming that the government's position was that the most frequent method of obtaining a controlled

no control over and are not responsible for that type of patient-driven diversion. 5/26 Tr. at 196:7–11, 198:19–22 ("Q. You agree that when a patient misuses medication that was prescribed for a legitimate medical use, whether it's giving it away or selling it, the ***patient*** is responsible for that? A. Yes, sir. … Q. You agree that when a prescription is legitimately written and dispensed, distributors have no control over what happens to it after that point? A. That's a correct statement.").[15]

Plaintiffs' evidence demonstrates that opioid prescribing has decreased significantly in recent years: Dr. Gupta testified that opioid prescribing in West Virginia decreased by 52% between 2013 and 2019, *see* 5/6 Tr. at 58:7–11, and Dr. Lacey Keller's analysis of prescribing data showed that "after increasing from 1997 to 2010, opioid prescriptions in Cabell County generally fell from 2010 through 2017," 6/15 Tr. at 204:25–205:4. And Dr. Kevin Yingling—the Chair of the Cabell-Huntington Health Department's Board of Health—agreed that "the use of opioid prescriptions in Cabell County at this time is within the bounds of medically accepted practice." 6/16 Tr. at 170:5–12.

As the level of prescribing has declined, so too has the volume of Defendants' distribution. Dr. McCann's data analysis shows that Defendants' distribution into the two zip codes encompassing Cabell/Huntington (as well as parts of six other counties) has declined by two-thirds from its peak, and that "[distribution] levels in 2019 are about the same as back in [the] 2001 window":

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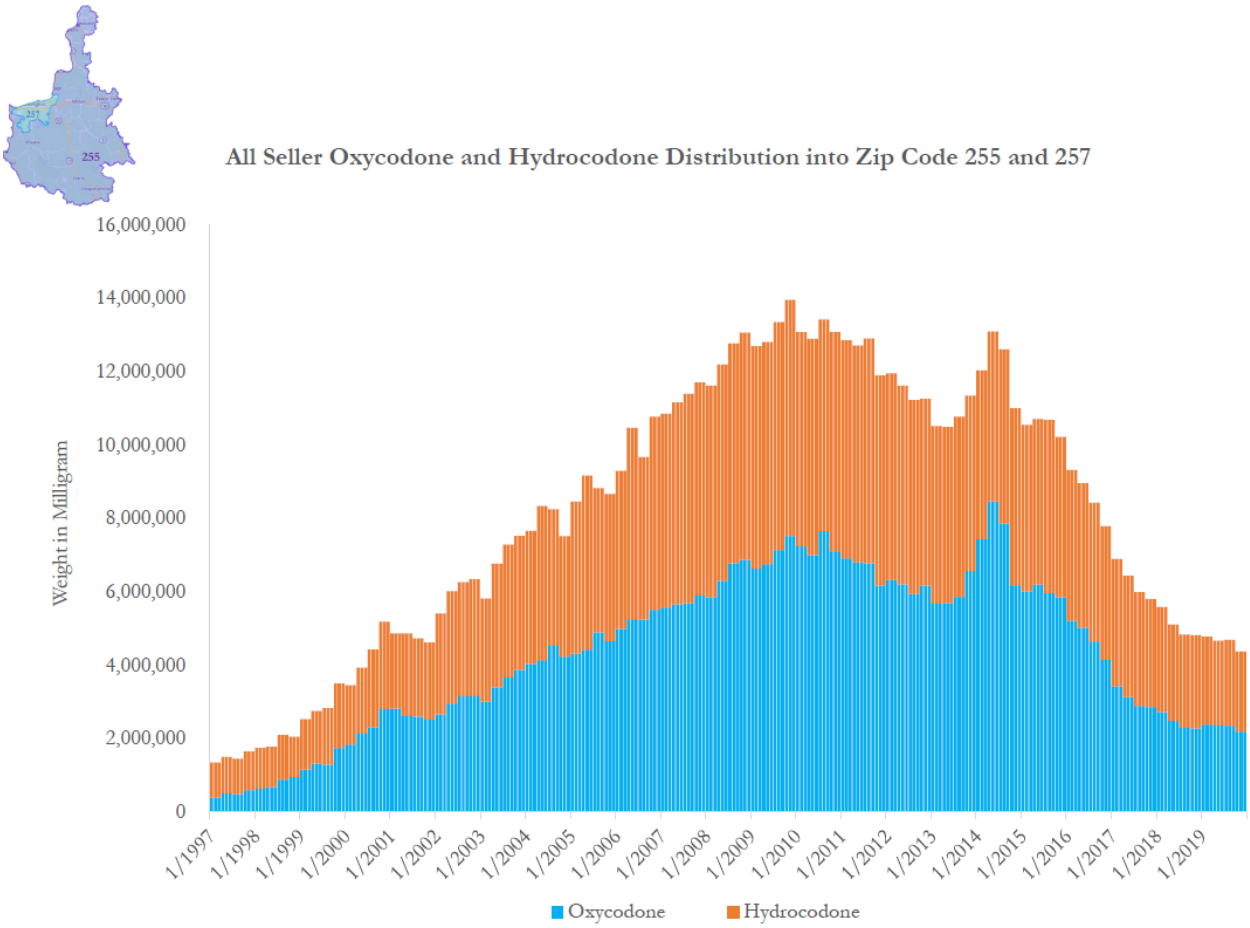
substance for non-medical use was through friends and family); Trial Ex. MC-WV-02079 (Compton 2019) at 6 (stating that more than half of people who misuse prescription opioids report obtaining them from friends or family members who have prescriptions).

[15] *See also* 6/9 Tr. at 141:24–143:23 (Mr. Rannazzisi agreeing that unreasonable volumes in prescriptions can lead to medicine cabinet diversion and that this can happen even if Distributors do everything they are supposed to).



See Trial Ex. P-44711 (McCann Data Analysis) at 12; 5/11 Tr. at 160:13–161:4.

Consistent with this decline in opioid prescribing and distribution, the evidence developed in Plaintiffs' case demonstrates that—since no later than 2013—opioid-related harms in Cabell/Huntington have been caused almost entirely by illegal opioids like heroin and illicit fentanyl. Beginning in the 2012/2013 timeframe, there was a sharp increase in ***illegal*** opioid overdoses both nationally and in Cabell/Huntington.[16] Accordingly, in both 2013 and 2014, the Huntington Police Department ("HPD") stated that "the growing use of heroin is the ***number one***

[16] *See, e.g.*, 5/4 Tr. at 176:22–177:5 (Dr. Waller agreeing that "[t]here was a marked increase in overdose deaths from illicitly made synthetic opioids generally related to Fentanyl beginning in 2013"); 5/5 Tr. at 82:9–83:3 (Dr. Gupta testifying that heroin-related overdoses "started to spike quite significantly from 2012 onward").

threat to the City of Huntington."[17] Multiple fact witnesses—including former HPD data analyst Scott Lemley and Sherriff Zerkle—have described how heroin and illicit fentanyl-related harms overtook prescription opioids as the cause of the current opioid-related harm in Cabell/Huntington.[18]

Put simply, the evidence shows that there is an ***illegal*** opioid problem in Cabell/Huntington today, not an ongoing prescription opioid problem. But Defendants do not distribute illegal opioids like heroin and illicit fentanyl. Instead, the evidence shows that criminal drug trafficking organizations from China and Mexico have trafficked illegal opioids into Cabell/Huntington,[19] and that criminal drug dealers from places like Detroit and elsewhere have preyed on Cabell/Huntington,[20] including by lowering the price of heroin and adulterating heroin with high-

[17] *See* Trial Ex. P-41252 (HPD 2013 Annual Report) at 22; Trial Ex. P-41220 (HPD 2014 Annual Report) at 17.

[18] *See* 5/21 Tr. at 129:7–16 (Mr. Lemley describing how prescription opioids were a problem in the 2011/2012 timeframe, but were "overtaken by heroin" in the 2014/2015 timeframe), *id*. at 218:2–14 (Mr. Lemley testifying that Huntington's 2017 Strategic Plan did not contain any mention of stopping prescription opioid shipments because "we had moved on from that point" and "progressed to heroin and … fentanyl and carfentanil"), *id*. at 238:1–18 (Mr. Lemley testifying that heroin was the number one threat to Huntington as of 2013); 5/27 Tr. at 149:12–14 (Sherriff Zerkle testifying that in his experience, he was seeing "[p]redominantly heroin" in 2017).

[19] *See, e.g.*, 5/4 Tr. at 179:6–18 (Dr. Waller agreeing that "[t]he shift from southeast Asian heroin to, in particular, Mexican heroin facilitated the proliferation of heroin in communities across the United States"); 5/6 Tr. at 84:14–19 (Dr. Gupta testifying that "foreign nations … are responsible for, for fentanyl in this country").

[20] *See, e.g.*, Trial Ex. DEF-WV-00916 (Huntington Drug Market Initiative 6 Month Analysis) at 4–5 (describing how the elimination of HPD's drug unit "left the city in a vulnerable condition" which was "soon discovered by drug dealers from large Midwestern cities such as Detroit and Columbus"); Trial Ex. DEF-WV-01323 (FBI Huntington Violent Crime Drug Task Force funding proposal) at 2 ("[Huntington] is frequently referred to as 'Little Detroit' due to the large population of former Detroit based heroin traffickers. Huntington is a destination city known and utilized by Detroit violent gang members and narcotics traffickers to establish heroin distribution points in other parts of the Tri-State region.").

potency fentanyl analogues to save costs.[21] There is absolutely no evidence tying Defendants to any of this criminal conduct.

LEGAL STANDARDS

A. Rule 52(c)

In a nonjury trial, judgment is warranted when "a party has been fully heard on an issue" necessary to maintain its claim or defense and "the court finds against the party on that issue." Fed. R. Civ. P. 52(c); *see also, e.g.*, *Carter v. Ball*, 33 F.3d 450, 457 (4th Cir. 1994) ("A district court sitting without a jury may enter judgment as a matter of law against a party on any claim once the party has had a full opportunity to present evidence on that claim."); *First Va. Banks, Inc. v. BP Expl. & Oil Inc.*, 206 F.3d 404, 407 (4th Cir. 2000) (Rule 52(c) "authorizes the court to enter judgment at any time that it can appropriately make a dispositive finding of fact on the evidence").

"In deciding whether to enter judgment on partial findings under Rule 52(c), the district court is not required to draw any inferences in favor of the non-moving party; rather, the district court may make findings in accordance with its own view of the evidence." *Ritchie v. United States*, 451 F.3d 1019, 1023 (9th Cir. 2006). "The court's task is to weigh the evidence, resolve any conflicts in it, and decide for itself in which party's favor the preponderance of the evidence lies." Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure, § 2573.1 (3d ed. 2020); *see also EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 272 (3d Cir. 2010) (under Rule 52(c), "the district court applies the same standard of proof and weighs the evidence as it would at

[21] *See, e.g.*, 5/4 Tr. at 184:12–185:12 (Dr. Waller describing how drug dealers sell counterfeit pills made from heroin or fentanyl and adulterate heroin and other drugs with synthetic opioids to cut costs), *id*. at 205:13–21 (Dr. Waller testifying that the relatively lower price of heroin and fentanyl compared with prescription opioids contributed to the increase in illegal opioid-related harm); 5/6 Tr. at 225:19–20 (Connie Priddy—coordinator of the Huntington Quick Response Team—agreeing that drug cartels lace heroin with fentanyl).

the conclusion of the trial"); *M & M Poultry, Inc. v. Pilgrim's Pride Corp.*, 281 F. Supp. 3d 610, 620 (N.D. W. Va. 2017) ("Rule 52(c) expressly authorizes district judges to resolve disputed issues of fact."); *W.L. Gore & Assocs., Inc. v. Medtronic, Inc.*, 874 F. Supp. 2d 526, 540 (E.D. Va. 2012), *aff'd*, 530 F. App'x 939 (Fed. Cir. 2013) ("To grant JMOL under Rule 52(c), a district judge must weigh the evidence and resolve credibility.").

B. Proximate Causation

Plaintiffs concede that, while they need not prove Defendants "were the sole proximate cause" of the alleged public nuisance, they must prove that Defendants "were *a* proximate cause." *See* Pls.' Mem. of Law in Opp. to Defs.' Mot. for Summary Judgment on Proximate Causation Grounds (ECF No. 1080) at 5 (citing *Everly v. Columbia Gas of W. Virginia, Inc.*, 171 W. Va. 534, 536 (1982)) (emphasis in Plaintiffs' brief).[22] And, under West Virginia law, "remoteness is a component of proximate cause, which in turn embraces the concept that the 'judicial remedy cannot encompass every conceivable harm that can be traced to alleged wrongdoing.'" *Aikens v. Debow*, 208 W. Va. 486, 492, 541 S.E.2d 576, 582 (2000). Thus, it is well-established that the conduct "which renders a defendant liable for damages must be a proximate, ***not a remote***, cause of injury[.]" *Metro v. Smith*, 146 W.Va. 983, 990, 124 S.E.2d 460, 464 (1962).

To avoid judgment on proximate causation grounds, Plaintiffs must have evidence of a "***direct relation*** between the injury asserted and the injurious conduct alleged."[23] *Holmes v. Sec.*

[22] *See also, e.g.*, *State v. Chase Sec., Inc.*, 188 W. Va. 356, 364, 424 S.E.2d 591, 599 (1992) (recognizing "the common law tort concept that liability results from the violation of a duty owed which was a proximate cause of the plaintiff's injury"); *see also Farley v. Crystal Coal & Coke Co.*, 102 S.E. 265, 268 (W. Va. 1920) ("Each is liable only for the consequences of his own wrong.").

[23] In assessing whether there is a "direct relation" between claimed injuries and conduct, "[t]he general tendency of the law … is not to go beyond the first step" in the causal chain. *Holmes*, 503 U.S. at 271–72. A link that is "too remote" or "purely contingent" will not suffice. *Id.* at 271.

Inv'r Prot. Corp., 503 U.S. 258, 268 (1992); *see also Employer Teamsters-Local Nos. 175/505 Health & Welfare Tr. Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013) (applying the *Holmes* standard to West Virginia state law claims); *City of Charleston v. Joint Comm'n*, 473 F. Supp. 3d 596, 628 (S.D. W. Va. 2020) (discussing *Holmes* and concluding that "courts have applied the principles of remoteness to state law tort claims insofar as proximate cause requires 'carefully drawing a line so as to distinguish the ***direct consequences*** in a close causal chain from more attenuated effects influenced by too many intervening causes'"). Two prior decisions by courts in this District illustrate the principle:

- In *Employer Teamsters*, plaintiffs sued the manufacturers of a blood thinning medication, alleging that the manufacturers engaged in false and misleading marketing of the drug, leading to increased prescribing. 969 F. Supp. 2d at 465–66. Judge Chambers dismissed the plaintiffs' claims, concluding that "[b]etween Defendants' alleged misleading marketing and Plaintiffs' prescription reimbursements lies a vast array of intervening events, including the 'independent medical judgment' of doctors." *Id.* at 475. In doing so, Judge Chambers held that the "directness" standard from *Holmes* provided "guiding principles in assessing proximate causation" that should be applied to West Virginia state law claims. *Id*.

- In *City of Charleston*, plaintiff municipalities—including the City of Huntington—sued the body that accredits hospitals nationwide, alleging that its requirement that hospitals treat pain as "The Fifth 'Vital Sign'" and its issuance of opioid-friendly "Pain Management Standards" led to "inappropriate provision of opioids," which in turn caused the municipalities to incur increased health care costs and other injuries. 473 F. Supp. 3d at 606–07, 615–16. Judge Copenhaver held that the municipalities' state-law claims failed the *Holmes* direct injury test "given the numerous intervening events and parties standing between" defendant's misconduct and the municipalities' alleged injuries.[24] *Id.* at 630 (applying West Virginia law). In particular, the court emphasized that the "independent medical judgment of the prescribing physicians" as well as the "criminal actions of third parties," defeated proximate causation. *Id.* at 631; *see also id.* ("no injury would occur

[24] Although Judge Copenhaver observed that the defendant in *City of Charleston*—a healthcare accreditation organization—was even *further* removed in the causal chain than wholesale distributors, *see* 473 F. Supp. 3d at 630–31, he neither held nor suggested that proximate causation exists as to distributors. And indeed, the same independent actors whose intervening conduct defeated a showing of proximate causation in *City of Charleston*—*i.e.*, the doctors who wrote allegedly inappropriate prescriptions and the criminal actors who improperly diverted and abused prescription opioids—also establish the absence of proximate causation here.

unless the physician proceeded to unnecessarily prescribe opioid treatments or if patients obtained the drugs through some other illegal means").

Taken together, *Employer Teamsters* and *City of Charleston* confirm that proximate causation does not exist, and judgment is warranted, when numerous independent actors and events—including the independent judgments of medical professionals and the criminal acts of third parties—stand between the defendant's alleged misconduct and the plaintiff's alleged harm.

ARGUMENT

Plaintiffs seek to hold Defendants liable for an ongoing, present day nuisance that, they say, consists of widespread opioid addiction and abuse in Cabell/Huntington.[25] But the evidence shows that Defendants are not responsible for the increase in opioid prescribing that occurred beginning in the late 1990s. The evidence further shows that—since no later than 2013—Cabell/Huntington's opioid abuse problem consists overwhelmingly of illicit drug use. Accordingly, Plaintiffs have failed to demonstrate that Defendants' alleged wrongdoing was a proximate cause of either (1) Cabell/Huntington's long-concluded problem of widespread prescription opioid abuse or (2) its present-day illegal, non-prescription opioid abuse problem.

I. PLAINTIFFS HAVE NOT PROVEN THAT DEFENDANTS' ALLEGEDLY CULPABLE CONDUCT WAS A CAUSE OF THE USE OR ABUSE OF PRESCRIPTION OPIOIDS IN CABELL/HUNTINGTON.

Plaintiffs' claim is predicated on the assertion that Defendants shipped an "excessive" volume of prescription opioid pills into Cabell/Huntington, that a portion of those pills were subsequently diverted to the illicit market, and that a portion of the Cabell/Huntington residents

[25] Defendants disagree that the "public nuisance" at issue can be the "opioid epidemic" or "crisis." As explained in the Abatement Motion, filed contemporaneously herewith, a public nuisance consists of *conduct* that injuriously affects the public health or safety. *See* Abatement Mot. at Part I.B. Thus, Plaintiffs' framing of the nuisance in terms of the alleged downstream effects of Defendants' purportedly wrongful conduct is incorrect, but Defendants assume it to be true for purposes of this motion.

who illegally used those pills subsequently became addicted. This attenuated theory of harm requires the Court to ignore entirely the fact that ***doctors***, not wholesale distributors, were responsible for making prescribing decisions, and that even during the height of alleged overprescribing, the "overwhelming majority" of doctors were prescribing in good-faith. *See supra* p.5. There is no evidence that Defendants ever shipped more pills into Cabell/Huntington than were prescribed by doctors and, as Plaintiffs' expert Dr. Keyes admitted, "the opioid crisis ***would not have occurred*** if prescribing opioids had not become standard practice in managing acute and chronic pain." 6/14 Tr. at 82:19–22.

Despite the fact that Plaintiffs' claim is predicated on the assertion that Defendants shipped "too many" pills into Cabell/Huntington, Plaintiffs never presented any evidence regarding what the "right" number of pills was.[26] Distributors have no obligation, and no ability, to second-guess the prescribing of doctors. *See supra* n.9 & accompanying text. Thus, it was incumbent upon Plaintiffs (at a minimum) to demonstrate that Defendants shipped more pills than were necessary to meet the needs of the community as determined by the good-faith prescribing of Cabell/Huntington doctors. Yet Plaintiffs did not even attempt to do that.

[26] Plaintiffs' expert witnesses repeatedly disavowed having any opinion as to the "right" level of opioid supply in Cabell/Huntington. *See, e.g.*, 5/11 Tr. (McCann) at 66:3–9 ("Q. [Y]ou have not studied the medical needs for Cabell County or the City of Huntington; correct? A. Correct. Q. And you cannot tell this Court how many prescription opioids should have been distributed to Cabell County or the City of Huntington; correct? A. Correct."); 5/26 Tr. (Rafalski) at 129:4–7 ("Q. You've not done any kind of analysis of the medical needs for prescription opioids in Cabell County or Huntington relative to the national average; correct? A. That's a correct statement. I did not do that."); 6/14 Tr. at 19:20–20:10 (Dr. Keyes admitting that she "ha[s] not undertaken a statistical evaluation" of how many pills are needed in Cabell/Huntington and "ha[s] not undertaken any analysis of the pain needs specifically in Cabell/Huntington"); 6/15 Tr. (Keller) at 168:11–17 ("Q. So, you're not an expert who can come and tell the Court what volume of opioids was the right volume that should have been prescribed in Cabell-Huntington at any point in time, correct? A. Correct. … I don't offer the opinion of what should be the volume."); 6/17 Tr. at 48:21–49:1 (Dr. Thomas McGuire admitting that he "did not … determine an appropriate level of distribution of prescription opioids into Cabell and Huntington" as part of his expert analysis).

In short, because there is no evidence that (1) Defendants' alleged wrongdoing was the cause of the increase in the volume of pills shipped into Cabell/Huntington or (2) Defendants were the cause of any diversion that occurred in Cabell/Huntington, Plaintiffs have failed to come forward with sufficient evidence that Defendants were a proximate cause of prescription opioid addiction and abuse.

A. Defendants Did Not Cause the Increase in the Volume of Prescription Opioids in Cabell/Huntington.

The record evidence makes clear that Defendants were not a cause of the increase in the volume of pills during the time period from the late 1990s to the mid-2010s. Defendants never shipped more pills to any Cabell/Huntington pharmacy than were ordered by their pharmacy customers to fill prescriptions written by doctors. For example, Mr. Rafalski testified that opioid distributions went up (and later down) because prescriptions went up (and later down):

> Q. You get the prescription, that goes up, and then the distribution goes up, correct?
>
> A. That's correct. No other way for those charts to increase without prescriptions.
>
> Q. ***No other way, right?***
>
> A. ***That's correct.***

5/26 Tr. at 242:15–20. Similarly, Mr. Rannazzisi admitted that "what drives demand for opioids is appropriate medical treatment," not opioid supply, 6/9 Tr. at 87:23–88:1, 89:11–13, and Dr. McCann testified that prescribing and distribution volumes are "two sides of the same coin," 5/11 Tr. at 134:24–135:3. Dr. Keyes admitted that the increased volume of opioid prescriptions became "***the foundation*** for the overall expansion in the opioid supply and opioid-related harm," and that "the opioid crisis ***would not have occurred***" if doctors had not increased their prescribing. 6/14 Tr. at 82:10–22.

Thus, the evidence shows that Distributors did not cause the volume of pills in Cabell/Huntington to increase—prescriptions did. The volume of pills that Defendants shipped to their customers in Cabell/ Huntington began to rise in the late 1990s because doctors were in good faith writing, and patients were filling, a greater number of prescriptions, which in turn led pharmacies to include more opioid medicines in the orders they placed with Defendants.[27] The undisputed evidence demonstrates this change in the practice of medicine was caused by a change in the standard of care for prescribing opioid pain medication.

For most of the 20th century, medical professionals prescribed opioid pain medicines sparingly. Beginning in the 1980s, there were calls from some physicians and patient advocacy groups that not enough was being done to treat pain. 5/4 Tr. (Waller) at 172:7–16. And, beginning in the 1990s, the standard of care changed to recognize a broader range of appropriate uses for prescription opioids nationwide. *See, e.g.*, Trial Ex. MC-WV-02079 (Compton 2019) at 5; 5/4 Tr. at 94:9–20 (Dr. Waller admitting that there was a "sea change" in opioid medication prescribing that began in the mid-1990s and "hit its peak between 2010 and 2012").

[27] Plaintiffs have pointed out that there were more prescription opioids *shipped* to West Virginia and Cabell/Huntington than to other parts of the country. But the evidence shows that opioid *prescribing* rates in West Virginia and in Cabell/Huntington exceeded national and state averages. *See, e.g.*, 6/15 Tr. (Keller) at 200:10–23. And that is what explains why there were more prescription opioids shipped to West Virginia and Cabell/Huntington than other parts of the country. The undisputed trial testimony also shows why opioid prescribing, and therefore distributions, were higher in West Virginia and Cabell/Huntington. West Virginia doctors prescribe more medicine of all kinds, including prescription opioids, per person than do doctors in other states. *See, e.g.*, Trial Ex. DEF-WV-00747 (Public Health in West Virginia: Brief History and Current State of Health) at 38. Numerous demographic factors explain this increase in prescribing—including Cabell/Huntington's relatively aged population and the greater proportion of blue-collar jobs in the community—all of which are associated with higher levels of pain and illness, and thus greater opioid prescribing by doctors. *See, e.g.*, *Id.* at 24–25, 27, 38; 5/6 Tr. (Gupta) at 51:14–18 (agreeing that "more aged populations tend to have higher levels of pain" and testifying that "[a]s we age, one could have pain levels that could be higher").

For example, the Joint Commission on the Accreditation of Health Care Organization, which was the regulatory body that the federal government used to identify and evaluate hospitals for safety, played an important role in changing the standard of care. 5/4 Tr. (Waller) at 96:17–21, 97:10–16. In order for a hospital to participate in federal healthcare programs like Medicaid and Medicare, the hospital must be accredited by the Joint Commission. *Id*. at 96:22–97:1. In the early-to-mid 2000s, the Joint Commission made implementing "pain as the fifth vital sign" a criteria for accreditation, meaning that hospitals that received federal funding needed to comply. *Id*. at 97:2–9. Pain as a fifth vital sign referred to the practice of monitoring patient pain as closely as the traditional four vital signs—temperature, blood pressure, respiration and pulse—and more generally addressing pain management more aggressively. *Id*. at 96:1–8. The practice of pain as a fifth vital sign had a significant impact on opioid prescribing. *Id*. at 97:10–16; *see also* 6/16 Tr. at 182:16–20 (Dr. Yingling agreeing that "the addition of pain as the fifth vital sign and the smiley face/happy face diagram shown to patients had the effect of increasing net prescribing of pain medications").[28]

These nationwide changes were fully embraced by regulators and the medical community in West Virginia. For example:

[28] Similarly, DEA sets annual aggregate production quotas for each prescription opioid in the United States, based on its determination of the legitimate medical and scientific needs for prescription opioids in a given year. See 21 U.S.C. § 826; *see also* 6/9 Tr. (Rannazzisi) at 186:20–25. Based on its determination of an increased legitimate medical need for opioid medicines, DEA continuously increased aggregate production quotas for prescription opioids, thereby allowing more prescription opioids to be manufactured and distributed. *See* 6/9 Tr. (Rannazzisi) at 186:20–187:10, 187:20–188:9; *see also* Trial Ex. DEF-WV-01597 (2019 OIG Report) at 13 ("[F]rom 2003 to 2013, DEA authorized manufacturers to produce substantial amounts of opioids. For example, the Aggregate Production Quota (APQ) of oxycodone in the United States increased over 400 percent, from 34,482 kilograms in 2002 to a high of 153,750 kilograms in 2013." (citation omitted)), 45 ("[A]s the rate of opioid use and abuse in the United States continued to increase from 1999 to 2016, the amount of opioid manufacturing authorized by DEA also increased dramatically during that same time.").

- In 1997, the West Virginia Board of Medicine issued a "Position Statement on the Use of Opioids for the Treatment of Chronic Non-Malignant Pain." *See* Trial Ex. MC-WV-01219 (1997 Position Statement by the West Virginia Board of Medicine) at 1. That statement recognized that "opioids are appropriate treatment for chronic non-malignant pain in selected patients" and indicated that "[a] physician need not fear disciplinary action by the Board if complete documentation of prescribing of opioids in chronic non-malignant pain, even in large doses, is contained in the medical records." *Id*.

- In 2005, the Board adopted a "Policy for the Use of Controlled Substances for the Treatment of Pain" that encouraged physicians to "view pain management as a part of quality medical practice for all patients with pain, acute or chronic," and recognized that "controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins." *See* Trial Ex. MC-WV-01218 (2005 West Virginia Board of Medicine Guidelines) at 1–2.

- In 2008, the Board sent a copy of *Responsible Opioid Prescribing* by Dr. Scott Fishman to every doctor in the State.[29] *See* Trial Ex. DEF-WV-03616 (October 2008 Quarterly Newsletter) at 6 (stating that the West Virginia Board of Medicine, "in conjunction with the [FSMB]," among other organizations, "was able to distribute [*Responsible Opioid Prescribing*] to every licensed physician and physician assistant in West Virginia"). That book "asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient."[30] According to Plaintiffs, the guidelines promulgated by *Responsible Opioid Prescribing* and sponsored by the West Virginia Board of Medicine (and others) caused "widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches."[31]

As a result of this change in the standard of care—which was endorsed by the West Virginia Board of Medicine—doctors began to prescribe opioids for a broader range of conditions, most

[29] The State even went so far as to require doctors who were disciplined for improper opioid prescribing to read the book and write a report on it as a condition of maintaining their medical license. *See* 6/15 Tr. (Keller) at 267:12–269:9.

[30] Third Amend. Compl. ¶¶ 443, 569; *see also* Trial Ex. MC-WV-02111 (*Responsible Opioid Prescribing*) at 8–9.

[31] Third Amend. Compl. at ¶ 315; 5/4 Tr. (Waller) at 118:6–22 ("Q. Now, that's the same book that plaintiffs allege here misled doctors about the risks of prescribing opioids and causing them to overprescribe opioids; correct? A. That's correct.").

notably, for the long-term treatment of chronic pain.[32] Such prescribing, Dr. Waller testified, "was the ***general gestalt*** at the time given that pain as the fifth vital sign was being implemented in hospitals and as such that it was felt that that was the only lever we had to pull for the treatment of pain …." 5/4 Tr. at 103:11–20. Dr. Gupta—the former West Virginia Commissioner of Public Health—similarly testified that there was a "culture" among West Virginia and other doctors to prescribe more opioid pills than were required to treat the pain needs of patients. 5/6 Tr. at 89:8–90:19. And as Dr. Joseph Werthammer of Marshal University ruefully acknowledged in 2016, "it was not big pharma who wrote the prescriptions. It was me and my colleagues[.]" 5/21 Tr. at 31:8–32:1.

The undisputed testimony also shows that doctors who were prescribing in accordance with that "general gestalt" and "culture" were "acting in good faith." 5/4 Tr. (Waller) at 104:19-20. For instance, Dr. Gupta testified that most doctors thought they were doing the right thing: "[t]heir intent was to help their patient because that was the culture. That was the education. That was the influence. That was their understanding." 5/6 Tr. at 94:4–10. Similarly, as Mr. Rafalski acknowledged, DEA publicly stated at the time that 99% of doctors were acting in good faith—or, as Mr. Rannazzisi put it, were "perfect." 6/9 Tr. at 99:17–100:13, 102:4–10. And Dr. Keyes, who admitted that "the overwhelming majority of doctors prescribe opioids to their patients in good faith," 6/14 Tr. at 71:3–7, 76:8–15, also admitted that the flip-side of the coin—*i.e.*, intentionally

[32] *See* Trial Ex. MC-WV-02079 (Compton 2019) at 5; *see also* Trial Ex. P-44223 (2018 Opioid Response Plan for the State of West Virginia) at 9 ("A critical factor in fueling the national opioid epidemic is the rapid rise in opioid prescriptions for pain. From 1999 to 2012, opioid prescribing increased fourfold … West Virginia has experienced some of the highest rates of opioid prescribing in the nation."); 5/21 Tr. at 27:10–16 (Dr. Werthammer agreeing that "during that period where pain was considered the fifth vital sign, … opioids [were] prescribed more liberally").

inappropriate prescribing by "pill mills"—"do[es] not explain in any significant way the expansion of opioid prescribing and opioid-related harm in the U.S." 6/14 Tr. at 131:11–22.

Notably, there is no evidence that Defendants played any role in bringing about the change in the standard of care that led to the increase in opioid prescribing in the nation generally, or in Cabell/Huntington specifically. While Plaintiffs allege that a purportedly fraudulent marketing campaign by pharmaceutical ***manufacturers*** increased the number of opioid prescriptions written by doctors and filled by patients, *e.g.*, Third Amend. Compl. ¶¶ 374–76, 388–511, 538–650, there is no evidence (and no allegation) that Defendants played any role in that marketing campaign. Indeed, Plaintiffs' putative marketing expert, Dr. Jakki Mohr, admitted that she has no opinion that any of the so-called "marketing" messages made or delivered by Defendants misrepresented the risks, benefits, or addictive properties of prescription opioid medicines. *See, e.g.*, 6/11 Tr. at 97:3–5 ("Q. [Y]ou don't have any opinion here today that anything was false or misleading, correct? A. Correct. I have no opinion on that."). And as Dr. Mohr further admitted, "there's nothing improper" or "unusual" about the bare fact that Defendants engaged in "marketing" of their services to pharmacies. 6/11 Tr. at 112:19–113:3.

Nor is there any evidence that Defendants, as wholesale distributors, have either the duty or the ability to second-guess the good-faith medical judgments of doctors to prescribe greater quantities of pain medicines. Indeed, even Plaintiffs' own witnesses testified that it is ***not*** the role of wholesale distributors to intervene in these medical judgments. For example, Mr. Rannazzisi testified:

> Q. [***Distributors***] ***don't evaluate a patient's legitimate medical need for opioids in terms of deciding whether the opioids are appropriate for that patient***, correct?
>
> A. ***That's correct***.

> Q. They can't second-guess legitimate medical decisions by prescribers, correct?
>
> A. I don't understand when they would be questioning a legitimate medical prescription.
>
> Q. And they don't have access to individual patient medical records because of privacy laws, correct?
>
> A. They wouldn't have access to that.

6/9 Tr. at 154:17–155:2; *see also* 5/26 Tr. at 117:8–12 (Mr. Rafalski agreeing that "[t]he DEA does not expect distributors to second-guess the legitimate medical judgments of prescribers"), 149:3–13 (Mr. Rafalski agreeing that distributors "don't have access to individual patient prescriptions or individual patient data" and "don't have the information to evaluate the medical need of an individual patient"); 5/4 Tr. at 88:1–21, 90:19–21 (Dr. Waller testifying that wholesale distributors do not make prescribing decisions and do not interact directly with patients); 6/16 Tr. at 188:2–5 (Dr. Yingling admitting that "distributors do not interact with doctors as it relates to the care and treatment of individual patients").

To be sure, several of Plaintiffs' witnesses suggested that the volume of prescription opioid pills shipped to Cabell/Huntington was too high. But no Plaintiff witness ever even purported to identify what the proper volume should have been during the period of increased prescribing—*i.e.*, how may pills Defendants should have shipped based upon the medical needs of the community as determined by the contemporaneous, good-faith judgment of the Cabell/Huntington medical community. *See supra* n.26 & accompanying text.[33]

[33] While Mr. Rafalski at times suggested that Defendants should not have shipped the orders he flagged, he later disavowed that position after being asked how many cancer patients would be denied treatment by his flagging methodology. 5/26 Tr. at 217:15-17 ("It's not saying that none of these 90 percent would actually have been distributed[.]"). Moreover, Mr. Rafalski forthrightly admitted that his flagging methodologies did not take into account the medical need for prescription opioid medications. *See infra* p.30–31. Accordingly, even if accepted, Mr. Rafalski's testimony does not provide an answer to this question.

In sum, while Plaintiffs allege that there was a "flood" of prescription opioids in Cabell/Huntington, which resulted in downstream harm from opioid abuse and overdose, the record evidence shows that the so-called "flood" was caused by an increase in good-faith prescribing by doctors. In other words, the allegedly excessive volume about which Plaintiffs complain resulted from the decisions of the medical community in Cabell/Huntington and across the country, ***not*** wholesale distributors. Accordingly, even if the Court credits the opinion of Plaintiffs' expert epidemiologist, Dr. Keyes, that there is a causal relationship between the availability of opioids in the community (which she sometimes refers to as opioid distribution) and opioid-related harms, *see, e.g.*, 6/11 Tr. at 217:15–22, that opinion does nothing to satisfy Plaintiffs' burden to prove a causal relationship between Defendants' alleged wrongdoing and opioid-related harm. Because such alleged wrongdoing was not a proximate cause of the increase in opioid availability in the community, it cannot be the proximate cause of any harms that flow from that increase.[34]

B. There Is No Evidence Tying Defendants' Alleged Wrongdoing To Plaintiffs' Injury.

Plaintiffs argue that Defendants failed to meet an obligation to prevent diversion, and claim harm based on addiction and other injuries that allegedly flowed from the use of diverted prescription opioids by Cabell/Huntington residents. But (with the exception of a single pharmacy with which Defendants did not do business) there is no record evidence of where any diversion in Cabell/Huntington occurred. And Plaintiffs certainly did not present any evidence that any

[34] For this same reason, Defendants are not the proximate cause of any harm relating to individuals who allegedly transitioned from prescription opioid use to illegal opioid use as a result of the so-called "gateway theory." Even if the Court credits the gateway theory, that theory is irrelevant to proving proximate causation as to the predicate prescription-opioid related harms allegedly suffered by the Plaintiffs. *See infra* p.35–37.

wrongful conduct by Defendants was the cause of any diversion in Cabell/Huntington.[35] Accordingly, Defendants are entitled to judgment on proximate causation grounds.

1. Medicine cabinet diversion

Plaintiffs' experts concede that the principal form of prescription opioid diversion is "medicine cabinet" diversion, such as when a patient sells or gives away his medicines or a family-member takes them from the medicine cabinet. But, as those same experts admit, wholesale distributors have no ability and no responsibility for preventing diversion that takes place after pills are properly dispensed by pharmacists to patients.

The scientific literature makes clear that a majority of those who misuse prescription opioids obtained them from friends or family members. Trial Ex. MC-WV-02079 (Compton 2019) at 6; *see* Trial Ex. MC-WV-02096 (CDC Policy Impact Presentation) at 7 (stating that "[a]lmost all prescription drugs involved in overdoses come from prescriptions originally" and that "[m]ore than three out of four people who misuse prescription painkillers use drugs prescribed to someone else"); *see also* 6/14 Tr. (Keyes) at 37:6–38:6. Indeed, that was the official position of the U.S. government. 6/9 Tr. at 141:3–10 (Mr. Rannazzisi confirming that the government's position was that the most frequent method of obtaining a controlled substance for non-medical use was through friends and family). The testimony of Plaintiffs' own experts was in accord.[36] Thus, there is no

[35] Addiction can also occur when patients use or abuse medicines prescribed in good faith by their doctors, but there is no allegation and no evidence that Defendants are responsible for that.

[36] *See, e.g.*, 5/4 Tr. at 174:23–175:5 (Dr. Waller describing how diversion of unused opioid pills occurs between friends and family members); 5/6 Tr. at 91:14–25 (Dr. Gupta describing how the oversupply of prescription opioids caused by doctor overprescribing went unused and ended up being diverted from patients' medicine cabinets); 5/26 Tr. (Rafalski) at 196:12–21 (taking no issue with statistics showing that "[m]ore than three out of four people who use or misuse prescription painkillers use drugs prescribed to someone else").

real dispute that the main form of opioid diversion in both Cabell/Huntington and nationwide was "medicine cabinet" diversion.

As Plaintiffs' experts admit, however, Defendants do not have the role or ability to prevent medicine cabinet diversion. For example, Mr. Rafalski testified that medicine cabinet diversion is the responsibility of ***the patient***, not the wholesale distributor who supplied the patient's pharmacy:

> Q. You agree that when a patient misuses medication that was prescribed for a legitimate medical use, whether it's giving it away or selling it, the patient is responsible for that?
>
> A. Yes, sir.
>
> …
>
> Q. You agree that when a prescription is legitimately written and dispensed, distributors have no control over what happens to it after that point?
>
> A. That's a correct statement.

5/26 Tr. at 196:7–11, 198:19–23. Mr. Rannazzisi similarly testified that it is not the role of distributors to "evaluate a patient's legitimate medical need for opioids" and that distributors are not required to "Know [Their] Customer's Customer"—*i.e.*, the patients who obtain prescription medicines from pharmacies. 6/9 Tr. at 154:14–20, 155:3–7; *see also* 5/4 Tr. at 88:1–88:12 (Dr. Waller testifying that the decision whether to prescribe opioids for a patient is shared between the physician and the patient, and that distributors are not involved).

Even if it could be argued that Defendants' allegedly wrongful conduct allowed too many pills to be distributed to Cabell/Huntington, any connection between Defendants' alleged wrongdoing and medicine cabinet diversion is too remote and attenuated as a matter of law. *See, e.g.*, *Employer Teamsters*, 969 F. Supp. 2d at 475; *City of Charleston*, 473 F. Supp. 3d at 630–31. The record evidence makes clear that, where medicine cabinet diversion is concerned, the independent actions of at least four separate individuals stand between Defendants and any harm.

These include the medical judgments of two different professionals and at least two separate criminal acts:

1. Prescribing: Defendants cannot and do not diagnose, treat, or prescribe for patients.[37] That is the job of a licensed, registered physician who is empowered to exercise medical judgment. *See* 21 C.F.R. § 1306.04(a). No opioid medicines can leave a pharmacy shelf lawfully without a prescription.[38] Defendants have no ability to review or second-guess the validity of those prescriptions.[39]

2. Dispensing: Defendants cannot and do not dispense opioid products to patients.[40] That is the job of a licensed, registered pharmacist, who must operate in compliance with his/her own professional and regulatory duties not to fill illegitimate prescriptions. *See* 21 C.F.R. §§ 1306.04(a), 1306.11.

3. Diversion: Prior to their illicit use, the FDA-approved medicines delivered by Defendants to state-licensed pharmacies must be diverted to the illicit market—most often, according to Plaintiffs' experts, via the patient to whom the medicines legitimately were prescribed. *See supra* p.24 & n.36. That act of diversion—whether the patient willingly gives them away or sells them or someone else steals them—is explicitly prohibited by law,[41] and necessarily takes place ***after*** the drugs have left the pharmacy shelves and are no longer under Defendants' control.

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[37] *See, e.g.*, 5/4 Tr. at 88:1–12 (Dr. Waller testifying that the decision whether to prescribe opioids for a patient is shared between the physician and the patient, and that distributors are not involved); 5/21 Tr. at 22:14–18 (Dr. Werthammer agreeing that "these three defendants do not prescribe prescription opioids").

[38] *See supra* n.11 & accompanying text.

[39] *See supra* n.9 & accompanying text.

[40] *See, e.g.*, 5/26 Tr. at 131:11–132:19 (Mr. Rafalski explaining how pharmacies are responsible for dispensing opioids and have a regulatory responsibility to ensure that a "prescription was issued for a legitimate medical need," and confirming that wholesale distributors do not have any such role or responsibility), 148:22–149:5 ("Q. [Distributors] don't fill prescriptions brought to them. That's the role of the pharmacy. Correct? A. That's correct, Your Honor. Q. They don't check the prescriptions that patients bring into a pharmacy; correct? A. That's a correct statement. Q. In fact, they don't have access to individual patient prescriptions or individual patient data; correct? A. That's a correct statement.").

[41] *See* 21 U.S.C. § 841(a) (prohibiting the distribution of any controlled substance except as authorized by the Controlled Substances Act); *see also* 6/17 Tr. (Holbrook) at 243:12–15 ("Q. So, you've talked about diversion. So, let's just, for the record, lay it out there. Diversion is a crime, correct? A. Yes.").

4. Illicit Use: The harms that Plaintiffs attribute to Defendants cannot occur absent the use of a diverted prescription opioid. The possession and use of diverted pills without medical authority or a legitimate prescription is a criminal act.[42]

Only after all these actions occurred could any of those harms possibly occur, even if Defendants shipped "too many" pills.

City of Charleston and *Employer Teamsters*, discussed *supra* pp.12–14, illustrate the point. In both cases, courts in this District dismissed claims on proximate causation grounds, concluding that too many intervening events and third-parties stood between the defendants' alleged conduct and the plaintiffs' alleged harm. *See City of Charleston*, 473 F. Supp. 3d at 630–31 (holding that proximate cause was not satisfied because "numerous intervening events and parties st[ood] between" the Joint Commission's alleged misconduct and the municipalities' alleged injuries, including the independent medical judgment of doctors and the criminal actions of third-party drug dealers); *Employer Teamsters*, 969 F. Supp. 2d at 475 (holding that proximate cause was not satisfied because "a vast array of intervening events, including the 'independent medical judgment' of doctors" stood between the manufacturers' allegedly misleading marketing and any of plaintiffs' alleged harm). Just as in those cases, the evidence here demonstrates that the prescription opioid medicines shipped by Defendants to DEA-registered and State-licensed dispensaries would have sat on a shelf, causing harm to no one, but for the intervening actions of numerous third parties, including (1) the doctors who wrote the prescriptions, (2) the pharmacists who dispensed the pills, and (3) the criminal actors who diverted the pills and (4) the end-users who illegally used and abused the diverted pills. As such, "[D]efendants' actions are too attenuated

[42] *See, e.g.*, 5/5 Tr. (Gupta) at 112:8–15 ("Q. And when you talk about the fact that this indicated diversion, what do you mean about—what does that mean? A. So, if I have controlled substances in my possession but I don't have a prescription and there's no documentation of me getting a prescription, going to a doctor, filling a prescription at the pharmacy, that means one thing; I got it through illegitimate means. And that's what we call diversion.").

and influenced by too many intervening causes" to be a proximate cause of any injury allegedly suffered by Cabell/Huntington. *City of Charleston*, 473 F. Supp. 3d at 631.

2. Pharmacy-level diversion in Cabell/Huntington

Diversion can also occur at the pharmacy-level, *i.e.*, if a pharmacy is dispensing in the absence of a legitimate prescription. But there is ***no record evidence*** tying Defendants' alleged wrongdoing to any pharmacy-level diversion in Cabell/Huntington.

Over the course of nearly seven weeks, Plaintiffs offered the testimony of more than 30 fact and expert witnesses. None of those witnesses offered any evidence that diversion was occurring at any of Defendants' pharmacy customers in Cabell/Huntington. For example, Mr. Rannazzisi testified that he (1) "ha[d] not reviewed any documents related to West Virginia" and therefore could not identify "any orders in Huntington or Cabell County that [he] believed … should have been blocked by one of the defendants but were not." 6/9 Tr. (Rannazzisi) at 14:6–17.[43] To the contrary, the only record evidence regarding pharmacy-level diversion in Cabell/Huntington related to the A-Plus Care Pharmacy in Barboursville, which was "a major source of supply for pharmaceutical diversion to the tri-state area and beyond" and was shut down by local law enforcement in 2014.[44] The record shows that no Defendant ever supplied the A-Plus Care Pharmacy. *See, e.g.*, 5/26 Tr. (Rafalski) at 152:2–22 (acknowledging that Miami-Luken was the only supplier of the A-Plus Care Pharmacy).

[43] According to Mr. Rannazzisi, each Defendant had an obligation to block orders that were likely to be "diverted … somewhere down the road." 6/7 Tr. at 216:13–18. Thus, his inability to identify orders that Defendants should have blocked is tantamount to an admission that he could not identify any orders that were likely to be diverted.

[44] *See* Trial Ex. P-41220 (HPD 2014 Annual Report) at 20.

Nor did any of the testimony offered by Plaintiffs' experts establish any pharmacy-level diversion in Huntington/Cabell. For example, Dr. McCann offered testimony regarding the total volume of oxycodone and hydrocodone that Defendants shipped to certain of their customers in Cabell/Huntington. But he did not offer any opinions regarding whether those shipments were improper or diverted.[45]

For his part, Mr. Rafalski expressly disavowed any knowledge of pharmacy-level diversion in Cabell/Huntington:

> Q. You're not offering any opinions about whether diversion occurred at a pharmacy level; correct?
>
> A. I haven't put that opinion in my report, so I guess that's a true statement, Your Honor.

5/26 Tr. at 135:10–13. While he nevertheless offered the *ipse dixit* opinion that approximately 90% of the orders placed by Defendants' pharmacy customers prior to 2018 (1) should have been blocked by Defendants and (2) were "more likely than not" diverted, the sole basis for that facially implausible assertion is that these millions of orders were all flagged by his "Method A."[46] For the reasons stated in Defendants' renewed *Daubert* motion on Mr. Rafalski, ECF No. 1386, the Court should exclude Mr. Rafalski's opinions. But even if the Court considers his testimony, the

[45] *See, e.g.*, 5/11 Tr. (McCann), 65:17–66:13 (Dr. McCann testifying that he "ha[s] not studied the medical needs for [Cabell/Huntington]," "cannot tell this Court how many prescription opioids should have been distributed to [Cabell/Huntington]," and "cannot say whether or not all the charts [he] showed over the last day and a half show over-supply or under-supply").

[46] Mr. Rafalski's "Method A" flags any order whose total volume exceeds (even by one pill) the largest order placed by a pharmacy in the preceding 6 months—effectively imposing for all time a monthly cap that can never exceed the largest order placed in the first six months of ordering, no matter how long ago that was or whether circumstances have changed over time. 5/26 Tr. at 231:15–232:2. In addition, Method A "***assum*[*es*] that distributors did not conduct any diligence on the first flagged suspicious order," and therefore flags ***all*** subsequent orders—no matter how small or innocuous—placed by the same pharmacy for all time. 5/26 Tr. at 227:1–9.

testimony is not credible and does not provide the evidence Plaintiffs need for a judgment in their favor.

Mr. Rafalski admitted that he:

- did not know "how many" of the "suspicious orders that have occurred over time" were "actually diverted," 5/26 Tr. at 205:18–22;
- did not "actually review any of the orders" that he concluded "were likely to be diverted" before rendering his opinions, 5/26 Tr. at 214:13–15, 215:1–7;
- did not identify "a single doctor … in Cabell County or Huntington who was prescribing improperly or engaging in diversion," 5/26 Tr. at 128:11–15;
- was not "aware of any pills that were shipped by [Defendants] that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription," 5/26 Tr. at 131:6–10;
- ignored the admitted fact that, from 2003 to 2013, DEA was steadily increasing its production quota for prescription opioids, based on its determination that there was a growing medical need for the medicines, 5/26 Tr. at 180:7–181:1, 181:14–182:1;
- did not know what percentage of the orders he identified as likely to be diverted "were actually investigated and … cleared" by Defendants, 5/26 Tr. at 228:21–229:6; and
- is unaware of anyone in the real world, including DEA or wholesale distributors, ever adopting his methodologies, 5/26 Tr. at 220:14–19.

Finally, it bears particular emphasis that Mr. Rafalski made no effort to account for the admitted fact that an increase in opioid prescribing by doctors caused a substantial increase in the volume of orders placed by pharmacies in Cabell/Huntington over the time-period covered by his analyses. 5/26 Tr. (Rafalski) at 242:6–20. He did not assess the medical need for prescription opioid medications in Cabell County, does not "know how many of those orders went to fill legitimate medical need," and "ignore[d] entirely what the medical community [wa]s doing in terms of increased legitimate prescriptions." 5/26 Tr. at 129:4–7, 216:13–18, 216:23–217:1, 218:15–20, 242:1–5. He could not say, for instance, how many patients with cancer, or recovering from surgery, or dealing with end-of-life pain would have been deprived of vital medicines if

Defendants had, in fact, blocked a full 90% of all orders for opioid medicines they received from pharmacies in Cabell/Huntington. 5/26 Tr. at 217:2–218:14. Accordingly, Mr. Rafalski has no basis upon which to opine—and he did not opine—that, had Defendants done additional diligence on his flagged orders, they would have concluded anything other than that the orders were based prescriptions written by doctors ("nearly every" one of which, he concedes, was written "for a legitimate medical purpose," 5/26 Tr. at 120:21–121:9).[47]

In short, if (as the undisputed record evidence shows) the overwhelming majority of the orders shipped by Defendants were placed by pharmacies to fill prescriptions written in good faith by doctors in accordance with the then-prevailing standard of care, Mr. Rafalski's assertion that almost all of those orders should have been blocked and were likely diverted is facially implausible. Indeed, Mr. Rafalski himself all-but-recanted that testimony after being asked how many cancer patients would be denied treatment under his flagging methodology. 5/26 Tr. at 217:15-17 ("It's not saying that none of these 90 percent would actually have been distributed."). The Court should not—and need not—credit Mr. Rafalski's assertions. *See, e.g.*, *EBC, Inc.*, 618 F.3d at 272 (under Rule 52(c), "the district court applies the same standard of proof and weighs the evidence as it would at the conclusion of the trial"); *see also Weisgram v. Marley Co.*, 528 U.S.

[47] Further undermining the reliability and plausibility of Mr. Rafalski's opinions is the fact that it was directly contradicted by the fact testimony of Mr. Rannazzisi. While Mr. Rafalski purported to identify "suspicious" orders based on a flagging methodology that mechanically applied a rigid numerical threshold that was entirely untethered from real-world events, 5/26 Tr. at 84:12–95:21, 96:10–16, 97:7–12, 231:9–14, Mr. Rannazzisi made clear that this was inappropriate. 6/8 Tr. at 111:11–24, 183:22–184:2; 6/9 Tr. at 81:11–13 ("A suspicious order is not just, oh, it's over the threshold. It could be over threshold because it's next to a cancer center or palliative care center, a hospital."). Unsurprisingly, therefore, while Mr. Rafalski reached the facially unreasonable conclusion that Defendants should have flagged millions of orders, 5/26 Tr. at 96:17–97:6, Mr. Rannazzisi made clear that a reliable methodology would flag only a small number of orders. *See* 6/7 Tr. at 219:15–17 ("The volume of suspicious orders that should [be reported] is *not a huge quantity of orders*. It shouldn't be like boxes of orders.").

440, 446 (2000) (affirming conclusion that defendant's motion for judgment as a matter of law should have been granted where testimony of plaintiffs' expert witness, which was the sole evidence supporting plaintiff's product defect claim, was "speculative and not shown to be scientifically sound").[48]

* * *

In sum, Plaintiffs have failed to come forward with any credible evidence that any of Defendants' pharmacy customers in Cabell/Huntington were knowingly dispensing the medicines delivered by Defendants in the absence of a good faith prescription or were otherwise facilitating diversion—let alone that any Defendant knew or should have known that such diversion was occurring. Accordingly, Plaintiffs have failed to prove that Defendants' distributions to pharmacies in Cabell/Huntington caused any diversion in Cabell/Huntington.[49]

[48] The testimony of Lacey Keller likewise cannot save Plaintiffs' claims. Ms. Keller opined that, had Defendants purchased certain commercially available data sets, they could have identified high-volume prescribers in Cabell/Huntington. *See, e.g.*, 6/15 Tr. at 67:2–12. But, as Ms. Keller further testified, she was not offering the opinion that Defendants had any obligation to do so or should have done so. 6/15 Tr. at 111:5–8, 159:13–160:9. Nor did any other Plaintiff witness offer that opinion. To the contrary, Plaintiffs' experts all agreed that wholesale distributors do not have any obligation to monitor prescribing decisions by doctors or to interfere in the doctor-patient relationship. *See supra* n.9 & accompanying text; *see also* 6/9 Tr. at 112:9–113:5 (Mr. Rannazzisi testifying that DEA did not "investigate [doctors] based on quantities").

[49] There is no evidence that Defendants' alleged wrongdoing outside Cabell/Huntington caused any of the injuries underlying Plaintiffs' claim. As this Court has recognized, evidence of diversion occurring at specific pharmacies outside Cabell/Huntington is irrelevant to this case, at least absent a "demonstrable nexus" between any such pharmacies and harm to Cabell/Huntington residents. *See* Memorandum Opinion and Order (ECF No. 1297) at 10. Because Plaintiffs failed to establish such a nexus as to any extraterritorial pharmacy, any evidence relating to those pharmacies would be irrelevant.

II. PLAINTIFFS HAVE NOT PROVEN THAT DEFENDANTS' ALLEGEDLY CULPABLE CONDUCT WAS A CAUSE OF THE ABUSE OF ILLEGAL OPIOIDS IN CABELL/HUNTINGTON.

There is no evidence that Defendants' alleged wrongdoing was a proximate cause of Cabell/Huntington's present-day, ***illegal*** opioid abuse problem. And this is particularly problematic because the sole relief sought by Plaintiffs is the "abatement" of an allegedly ongoing "public nuisance" purportedly consisting of addiction and other social ills stemming from the abuse of opioids by Cabell/Huntington residents.[50]

The record is clear that Cabell/Huntington does not currently have a prescription opioid abuse problem—and has not had one for at least eight years. Rather, the record shows that, at all times since 2013 (if not earlier), the opioid problem in Cabell/Huntington consists overwhelmingly of the use of heroin and illicit fentanyl by Cabell/Huntington. *See supra* pp.9–11.

The record is likewise clear that Defendants are not responsible for the trafficking of illegal, non-prescription opioids into Cabell/Huntington. Indeed, there is no evidence whatsoever that Defendants delivered heroin or illicit fentanyl to customers in Cabell/Huntington. Rather, the undisputed record reflects that these illegal, non-prescription opioids were trafficked into Cabell/Huntington by criminal drug cartels. *See, e.g.*, Trial Ex. MC-WV-02079 (Compton 2019) at 7–8. For instance, Dr. Waller testified that "[t]he shift from southeast Asian heroin to, in particular, Mexican heroin facilitated the proliferation of heroin in communities across the United States," 5/4 Tr. at 179:6–18, and Dr. Gupta testified that "foreign nations … are responsible for, for fentanyl in this country," 5/6 Tr. at 84:14–19. This is consistent with the documentary evidence, which shows that foreign and domestic drug trafficking organizations have preyed on

[50] *See supra* n.1.

Cabell/Huntington,[51] including by lowering the price of heroin and adulterating heroin with high-potency fentanyl analogues in order to save costs.[52]

In light of these undisputed facts, it is clear that the direct causes of Cabell/Huntington's illegal opioid abuse problem include (1) the criminal drug trafficking organizations that ship heroin and illicit fentanyl into Cabell/Huntington (oftentimes including heroin or other drugs surreptitiously laced with illicit fentanyl), (2) the criminal drug dealers who illicitly sell those drugs to Cabell/Huntington residents, and (3) the Cabell/Huntington residents who knowingly purchase and abuse illegal street drugs (oftentimes without knowing that those illegal drugs have been surreptitiously laced with illicit fentanyl). Defendants cannot be held liable for the conduct of these third party criminal drug traffickers, drug dealers, and drug users.[53]

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[51] *See, e.g.*, Trial Ex. DEF-WV-00916 (Huntington Drug Market Initiative 6 Month Analysis) at 4–5 (describing how the elimination of HPD's drug unit "left the city in a vulnerable condition" which was "soon discovered by drug dealers from large Midwestern cities such as Detroit and Columbus"); Trial Ex. DEF-WV-01323 (FBI Huntington Violent Crime Drug Task Force funding proposal) at 2 ("[Huntington] is frequently referred to as 'Little Detroit' due to the large population of former Detroit based heroin traffickers. Huntington is a destination city known and utilized by Detroit violent gang members and narcotics traffickers to establish heroin distribution points in other parts of the Tri-State region.").

[52] *See, e.g.*, 5/4 Tr. at 184:12–185:12 (Dr. Waller describing how drug dealers sell counterfeit pills made from heroin or fentanyl and adulterate heroin and other drugs with synthetic opioids to cut costs), 205:13–21 (Dr. Waller testifying that the relatively lower price of heroin and fentanyl compared with prescription opioids contributed to the increase in illegal opioid-related harm); 5/6 Tr. at 225:19–20 (Connie Priddy agreeing that drug cartels lace heroin with fentanyl).

[53] *See also, e.g.*, *Harbaugh v. Coffinbarger*, 209 W.Va. 57, 64 543 S.E.2d 338, 345 (2000) (decedent's decision to play Russian roulette was "[a]n intervening cause ... making it and it only, the proximate cause of the injury" even though defendant had supplied the loaded gun); *Yourtee v. Hubbard*, 196 W. Va. 683, 690, 474 S.E.2d 613, 620 (W. Va. 1996) ("Generally a willful, malicious, or criminal act breaks the chain of causation."); *Bertovich v. Advanced Brands & Importing, Co.*, 2006 WL 2382273, at *11 (N.D. W.Va. Aug. 17, 2006) (holding that "illegal acts of third parties breaks the necessary chain of causation"); *Ashworth v. Albers Med., Inc.*, 410 F. Supp. 2d 471 (S.D. W.Va. 2005) (drug manufacturer not liable for injuries caused by alleged criminal acts of third parties introducing counterfeit versions of the manufacturer's drug into the stream of commerce).

Without directly linking it to the heroin/fentanyl crisis in Cabell/Huntington, Plaintiffs have offered generic evidence about the so-called "gateway effect," or the idea that some number of people who use heroin or illicit fentanyl previously used prescription opioids. But for two reasons, even if the Court accepts that testimony (offered principally by an epidemiologist, Dr. Keyes), Defendants were not a ***legal*** cause of the illegal drug-related harms underlying Plaintiffs' claim.

First, for the reasons explained in Part I, Defendants were not a proximate cause of any prior prescription opioid abuse problem in Cabell/Huntington. Because Plaintiffs have failed to present sufficient evidence that Defendants proximately caused harms relating to legal prescription opioids, *see supra* Part I, Plaintiffs cannot possibly prove proximate causation as to harms caused by illegal opioids that are even further removed from Defendants' conduct. In other words, because Plaintiffs have not proven that any Defendant caused a Cabell/Huntington resident to become addicted to ***prescription*** opioids, the so-called gateway effect is irrelevant.

Second, any connection between Defendants' delivery of FDA-approved prescription opioids and harms flowing from the abuse of illegal opioids such as heroin and illicit fentanyl is too remote as a matter of law. Indeed, Dr. Keyes forthrightly admitted that, when a person dies of a heroin or fentanyl overdose, any prescription opioids that the person may have previously used is not a "proximal" cause of the death.[54] This testimony highlights the absence of a sufficiently direct connection between prior prescription opioid use and later harms resulting from the illicit use of non-prescription opioids.

[54] 6/14 Tr. at 121:14–19 ("Q. And when the death certificate does not list prescription opioids as a contributing cause of death, the Medical Examiner concluded that prescription opioids were not a source of the death, correct? A. A proximal cause of the death. It did not contribute to the death as it occurred.").

While Dr. Keyes purported to offer an opinion that prescription opioid use "causes" illegal heroin use, she used the term "causation" in a manner contrary to any legal standard. Dr. Keyes made clear that, under her definition, a "cause" (1) "need not be temporally proximate to the outcome[,]" (2) may be superseded by "an intervening cause … later in life," and (3) "does not need to be the closest or the most recent cause." 6/14 Tr. at 207:7–208:4. Dr. Keyes also testified that she's "not sure what's the direct cause," since that "is not terminology that [she's] familiar with." 6/14 Tr. at 208:14–17. Accordingly, even if the Court were inclined to accept Dr. Keyes' claims of causation as true under her definition, that does not establish ***legal*** or "proximate" causation.

As previously explained, in order to establish proximate causation, Plaintiffs were required to come forward with evidence of a "***direct relation*** between the injury asserted and the injurious conduct alleged." *Employer Teamsters*, 969 F. Supp. 2d at 473. By her own admission, Dr. Keyes's testimony did not establish a direct or proximate connection between Defendants' alleged misconduct and harms flowing from illicit drug use (or even between prior prescription opioid use and later illicit drug use). Nor did the testimony of any other witness even purport to address this question. Accordingly, Defendants are entitled to judgment irrespective of whether the Court accepts some version of Plaintiffs' gateway theory as true.

The *City of Charleston* case is again instructive. There, the court held that "defendants' actions [we]re too attenuated and influenced by too many intervening causes … to stand as the proximate cause of plaintiffs' injuries." 473 F. Supp. 3d at 631. In particular, the court concluded that the "criminal actions of third parties, such as 'illegal drug trafficking,'" rendered the claims too remote as a matter of law. *Id.* Likewise here, any connection between Defendants' distribution of FDA-approved prescription medicines to DEA-registered and State-licensed dispensers and any

harms flowing from the illicit use of illegal drugs such as heroin by Cabell/Huntington residents is too attenuated to satisfy proximate causation.

III. EVEN UNDER A FORESEEABILITY STANDARD, PLAINTIFFS HAVE FAILED TO PROVE PROXIMATE CAUSATION.

Plaintiffs likely will argue that the proper standard for determining whether Defendants' alleged wrongdoing was a cause of the injuries underlying their claims is "foreseeability." For two reasons, that argument cannot save their claims for judgment on causation grounds.

First, Plaintiffs are wrong on the law. It is well-established in West Virginia that "remoteness is a component of proximate cause[.]" *Aikens*, 208 W. Va. at 492; *see also Metro*, 146 W.Va. at 990 (the conduct "which renders a defendant liable for damages must be a proximate, ***not a remote***, cause of injury"). Consistent with that principle, courts in this District repeatedly have applied the *Holmes* "direct relation" standard to West Virginia state-law claims. *See, e.g.*, *Employer Teamsters*, 969 F. Supp. 2d at 475; *City of Charleston*, 473 F. Supp. 3d at 627–28.

Second, even accepting Plaintiffs' view of the law as true, they still have not met their burden. Plaintiffs have now completed their case. At this stage of the litigation, it is not enough for them to assert that diversion was the foreseeable consequence of Defendants' alleged wrongdoing. They need ***evidence*** that Defendants' wrongdoing actually led to the harms at issue in this case. And on that point, there is a wholesale failure of proof.[55] Accordingly, Defendants are entitled to judgment under Rule 52(c) even if the Court applies the causation standard advocated by Plaintiffs.

[55] Plaintiffs' failure of proof on foreseeability is especially acute where illegal, non-prescription opioids are concerned. There is absolutely no record evidence that Defendants could or should have foreseen that their delivery of FDA-approved medicines to DEA-registered pharmacies would lead to the widespread abuse of heroin and illicit fentanyl.

CONCLUSION

For the foregoing reasons, Plaintiffs have failed to prove that Defendants' alleged wrongdoing was a proximate cause of the injuries underlying Plaintiffs' claims, and Defendants are entitled to judgment on partial findings under Rule 52(c).

Dated: July 1, 2021

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 1st day of July, 2021, the foregoing "MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR JUDGMENT ON PARTIAL FINDINGS REGARDING PROXIMATE CAUSATION" was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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